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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/905,243 | 07/16/2001 | Alexander H. Taylor | P50770X1C1 | 4165 |

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EXAMINER

HELMS, LARRY RONALD

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/26/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/905,243 | TAYLOR, ALEXANDER H. |
| | Examiner Larry R. Helms | Art Unit 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 January 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,4,6 and 8-39 is/are pending in the application.
 - 4a) Of the above claim(s) 8-31 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3,4,6,32-35 and 39 is/are rejected.
- 7) Claim(s) 36-38 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 5 and 7 have been canceled.
Claim 1 has been amended.
Claims 32-39 have been added.
2. Claims 8-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 4.
3. Claims 1, 3-4, 6, 32-39 are under examination and will be examined to the extent the species of Pan troglodytes is the elected species of Old World apes.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains some NEW GROUNDS of rejection necessitated by amendment.

Rejections Withdrawn

6. The rejection of claims 1, 3-4 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
7. The rejection of claims 1, 3-4 and 6 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendments to the claims.

Response to Arguments

8. The rejection of claims 1, 3-4, 6 and newly added claims 32-35 and 39 under 35 U.S.C. 103(a) as being unpatentable over Newman et al (U.S. Patent 5,756,096, filed 6/7/95) and further in view of Vijh-Warrier et al (Molecular Immunology 32:1081-1092, 1995, IDS #7) and Adair et al (WO 91/0996, published 7/11/91) is maintained and made again.

The response filed 1/9/03 has been carefully considered but is deemed not to be persuasive. The response states that Newman et al teach frameworks from old world Monkeys not Old world Apes (see page 13 of response). In response to this argument, chimpanzees are Pan troglodytes as evidenced from Vijh-Warrier and as claim 6 states Old World Apes is Pan troglodytes. The response further states that Newman et al teach away from using pan troglodytes because they were interested in using an evolutionary distinct framework to avoid human anti-antibody response (see page 13 of response). In response to this argument, the passage in Newman cited (col 2, lines 19-25) is directed to producing antibodies in baboon which are significantly different from humans to produce an antibody response but have similar antibodies as those of humans. The passage does not teach away because Newman et al specifically teaches using chimpanzee constant regions or frameworks (see column 2, lines 8-10 and col 3, lines 38-41).

The response then continues to argue that Vijh-Warrier et al does not teach that framework residues from Old World Ape antibodies can be successfully used in an engineered antibody (see page 13 of response). In response to this argument, Vijh-Warrier et al specifically teach that chimpanzee Mabs are no more likely to elicit

deleterious anti-immunoglobulin responses in humans than human Mabs and emphasizes using chimpanzee-human chimeric Mabs (see page 1089).

The response further states that Adair et al does not teach the use of Old World Ape frameworks (see page 14 of response). In response to this argument, the Adair et al reference provides motivation to alter framework residues and Newman et al and Vijh-Warrier et al provide motivation to use frameworks from Old Word Apes.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (see page 14 of response), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 32-35 and 39 add limitations that would be obvious in view of Adair et al who teaches replacement of acceptor frameworks with donor and replacement of residues that influence the CDR and it would have been obvious to use human framework residues that are solvent exposed (see pages 20-23).

Conclusions

Art Unit: 1642

9. No Claims are allowed. Claims 36-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3559. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Art Unit: 1642

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to read "LARRY R. HELMS".